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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K00487.70006	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/US 03/11267	International filing date (day/month/year) 14.04.2003	Priority date (day/month/year) 12.04.2002
International Patent Classification (IPC) or both national classification and IPC G03B42/02		
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1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 29 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 12.11.2003	Date of completion of this report 27.07.2004
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EXAMINATION REPORT**

International application No. **PCT/US 03/11267**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

2-10, 12-19, 21-30, 33-39	as originally filed
11, 11a, 20, 20a, 31, 31a, 32, 32a	received on 14.08.2003 with letter of 12.08.2003
1	received on 15.12.2003 with letter of 11.12.2003

Claims, Numbers

10-33	received on 15.12.2003 with letter of 11.12.2003
1-9, 34-52	received on 28.05.2004 with letter of 28.05.2004

Drawings, Sheets

1/12-12/12	received on 24.09.2003 with letter of 12.08.2003
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2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 47-52

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. claims 47 to 47 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9-17, 41, 43-46
	No: Claims	1-8, 18, 24, 25, 29, 34, 42
Inventive step (IS)	Yes: Claims	9-17, 41, 43-46
	No: Claims	35 - 40
Industrial applicability (IA)	Yes: Claims	1-46
	No: Claims	

2. Citations and explanations

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Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question as to whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable has not been and will not be the subject of an international preliminary examination (Article 34(4)(a)(i) (ii) PCT) in respect of applications having an unnecessary plurality of independent claims (generally not more than 1 independent claim in the same category is necessary; Article 6 PCT).

Although claims 1 and 47 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1 and 47 do not meet the requirements of Article 6 PCT.

Moreover, the subject matter for which a protection is sought by claims 47 to 52 is an image, which as such is considered as a mere presentation of information (Rule 67 (v) and therefore regarded as subject matter under Article 34(4)(a)(i) for which no examination within the meaning of Article 33 PCT will be carried out

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1.1 **D1: US 5 123 040 A** discloses an X-ray film 9 having prior to exposure a marker 22 of radio-opaque material detectable in the image after exposure and being indicative of both which of the front side and the back side the plate has been exposed from (figures 1, 3a, 3b, column 2, line 38 to column 3, line 17: "...to identify the side of the film sheet facing the X-ray-tube during exposure." and column 4, lines 18 to 45). The known marker is clearly indicative of any mirroring transformations performed upon an image recovered from the plate after

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exposure, however, this is not a feature of the radiation recording plate itself to be defined by claim 1. It is a property of the image of the marker produced by the radiation, and this property is clearly shown also in D1 (see the above cited portions thereof).

- 1.2 Moreover, also **D2: CH 564 943 A** discloses a pen for marking radiographic plates prior to exposure in order to determine which side was facing the X-ray tube during exposure (column 1, lines 1 to 27; note that D2 mentions explicitly intraoral radiography, but this is not claimed, anyway, such a limitation, even if it were present, would not have been considered as involving an inventive step).

In view of these disclosures, the subject matter of **claim 1** and the corresponding method of **claim 34** do not appear new (Article 33(2) PCT).

- 1.3 Moreover, D2 explicitly mentions a suspension of a heavy metal in a binder to be applied to an X-ray film to identify the side from which it has been exposed as in the method of making a radiation sensitive plate according to claim 41 (see column 2, lines 9 to 13). However, D2 does not disclose to provide a further detectable marker on the first side of the plate, as also specified in the method of independent claim 41.

Hence, the subject matter of claim 41 is new with respect to D1 or D2 (Article 33(2) PCT).

- 2.1 Furthermore, D1 (column 4, lines 24 to 25) and D2 (column 1, lines 1 to 10) explicitly mention to use the marker in a region not interfering with a region of interest of the image as in claim 2, apart from that this is considered obvious anyway. A heavy element or an alloy or a salt of a heavy element as in claim 3 is also known from D1 (see above). Explicitly Ba is mentioned in D2, as in claim 4. As said above for independent claim 41, the medium suspended in a binder of claim 5 is also known from D2, as well as the asymmetries of claims 6, 7 or 8 (also known from D1).

Thus, claims 2 to 8 as well as the corresponding method claim 35 are not new (Article 33(2) PCT).

- 2.2 However, it appears that neither D1 nor D2 disclose a marker further comprising a

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back side marker according to claim 9. Hence, claims 9 and claims 10 to 17 depending from claim 9 are considered as new, and also to involve an inventive step with respect to D1 or D2, also when combining their teachings (Article 33(2) and 33(3) PCT).

3. The subject matter of claims 18, 24, 25, 29 and 35 do not appear to involve an inventive step in view of the above mentioned prior art (Article 33(3) PCT).
4. Moreover, **D3: US 6 354 737 B1** discloses the use of image processing software for reading and processing radiographic images to preserve the marker indicating the original image orientation during exposure during such image processing steps as rotating, flipping mirroring, as in claims 36 to 40.

Hence, also these steps (relating to an entirely different problem related to the use of software) do not appear to involve an inventive step within the meaning of Article 33(3) PCT.

5. The subject matter of claims 19 to 23 (probably relating to photo-stimulable phosphor sheets) and the directional marker as in claims 26 to 28 and 30 to 33 appear to involve an inventive step since the prior art documents D1 to D3 cited above or the other documents cited in the INTERNATIONAL SEARCH REPORT (INTERNATIONAL SEARCH REPORT (ISR)) do not contain indications to such subject matter. Hence, these claims satisfies the requirements of Articles 33(2) and 33(3) PCT.

The subject matter of all claims is obviously industrially applicable in the field of X-ray analysis, thus they comply with Article 33(4) PCT.

- 6.1 Independent claims 1, 34 and 41 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D2) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

In the present case, all the features of present claims 1, 34 or 41, respectively, are known in combination from the document D2 and belong in the preamble of such a claim.

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- 6.2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 6.3 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D3 is not mentioned in the description, nor are these documents identified therein.
- 6.4 The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT (pages 13 to 15).

- 40 -

CLAIMS

1. A radiation-recording plate constructed and arranged to have a capacity to form an image upon exposure from a front side and to have a capacity to form an image upon exposure from a back side, the plate including prior to exposure a marker that produces a mark detectable in the image after exposure and indicative of both which of the front side and the back side the plate is exposed from and indicative of any mirroring transformations performed upon an image recovered from the plate after exposure.

2. The plate of claim 1, the marker comprising a medium opaque to the radiation covering a region that does not interfere with a region of interest of the image when the plate is exposed from either side.

3. The plate of claim 2, sensitive to X-radiation, the medium comprising one of a heavy element, an alloy including a heavy element, a compound including a heavy element or a salt of a heavy element.

4. The plate of claim 3, the heavy element being one of Pb, Sn, Bi, I and Ba.

5. The plate of claim 2, sensitive to X-radiation, the medium suspended in a binder applied to the region.

6. The plate of claim 1, the marker having asymmetry about at least one axis.

7. The plate of claim 6, wherein the marker has horizontal asymmetry about a vertical axis relative to a normal image orientation.

8. The plate of claim 6, wherein the marker has vertical asymmetry about a horizontal axis relative to a normal image orientation.

9. The plate of claim 1, the marker further comprising a back side marker producing a mark in the image whose appearance in the image on the plate indicates exposure from the back side without interfering with a region of interest of the image.

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34. A method of identifying a side from which a radiation-recording plate having a capacity to form an image upon exposure from a front side and having a capacity to form an image upon exposure from a back side has been exposed to radiation, comprising:

5 incorporating in the plate prior to exposure, in a position that substantially does not interfere with an image area of the plate, a marker producing a mark whose appearance in an image identifies both which side the plate is exposed from and which is indicative of any mirroring transformations performed upon an image recovered from the plate after exposure;

exposing the plate to the radiation;

10 obtaining an image produced by exposing the plate to the radiation; and

observing the image for the identification of the side of the plate exposed and for the indication of any mirroring transformations.

35. The method of claim 34, further comprising:

15 arranging the marker to produce the mark so as to indicate whether the plate was flipped or rotated prior to exposing; and
observing the image for the indication.

36. The method of claim 35, further comprising:

20 observing the image using image processing software, the image processing software recognizing the mark and reorienting the image to have a clinically expected orientation.

37. The method of claim 36, further comprising:

25 storing with the image an indication of whether the image has been flipped an odd number of times.

38. The method of claim 36, further comprising:

substituting for the mark a replacement mark indicative of the software having processed the image;

30 storing the image with the replacement mark.

39. The method of claim 38, wherein substituting further comprises:

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arranging the replacement mark to be visible and asymmetric with respect to both axes whereby the replacement mark indicates an orientation of the image that is recognizable with respect to both axes.

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40. The method of claim 38, further comprising:
storing with the image an indication of whether the image has been reoriented by an odd number of times.

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41. A method of making a radiation sensitive plate having at least one radiation sensitive layer, comprising:

providing a film sensitive to the radiation on a first side of the radiation sensitive plate;

providing a detectable marker on the first side; and

15

applying a suspension of a heavy metal in a binder to a region of a second side of the radiation sensitive layer; wherein

the detectable marker and the suspension of a heavy metal applied combined are distinct and asymmetric.

20

42. The plate of claim 1, configured for use as radiography plate having a substantially smooth surface capable of producing a diagnostically useful image when exposed from either one of two sides.

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43. The plate of claim 42, wherein the feature comprises:

a front side marker producing a mark always apparent in the image; and

a back side marker producing a mark apparent in the image when the plate is exposed from the back side.

30

44. The plate of claim 43, wherein the mark produced by the back side marker at least partially overlaps the front side mark.

- 44/3 -

45. The plate of claim 44, wherein the mark produced by the front side marker and the mark produced by the back side marker are each asymmetric about two substantially perpendicular axes.

5 46. The plate of claim 45, included in a radiography system further comprising:
software defined by a computer executed sequence of instructions to:
store the image in an image file containing image data;
detect the mark in the image data;
10 arrange the image data for display in a selected arrangement relative to a
diagnostically expected orientation; and
store with the image file, distinct from the image data, an indication of the
selected arrangement of the image data.

15 47. An image stored on an image storage device, comprising:
a recording medium;
a record in the recording medium of an image produced by exposure of a radiation-
sensitive medium to the radiation; and
a mark embedded in the record of the image, the mark produced during the exposure
20 of the radiation-sensitive medium, and the mark both indicative of which side the radiation-
sensitive medium was exposed from and indicative of any mirroring transformations
performed upon the image in whose record the mark is embedded.

25 48. The device of claim 47, wherein the mark further comprises:
an indication of laterality immune to confusion by flipping and rotating the image.

49. The image storage device of claim 48, wherein the recording medium is the
radiation-sensitive medium.

30 50. The device of claim 48, wherein the record in the recording medium
comprises:
a digital signal representing the image held by the recording medium.

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51. The device of claim 50, further comprising:
a record of current orientation of the image, independent of the digital signal
representing the image.

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52. The image storage device of claim 48, wherein the indication of laterality
further comprises:
a record apparent upon viewing the image identifying unambiguously a current
orientation of the image.

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